

REMARKS/ARGUMENTS

The Claims

Claims 33-54 are currently pending in the application. Claim 45 has been allowed, Claim 46 has been objected to, and Claims 33-44 and 47-54 have been rejected.

Claims 33-35 have been amended to recite a "mature form" of a polypeptide. Support for the amendment is found at p. 40, line 15-17 of the specification where it is stated that a mature polypeptide is one lacking a signal peptide.

Claim 36 has been amended to recite "specifically" binding. Support for the amendment is found in original Claim 13 of the specification.

Claims 42-44 has been amended to recite "B7RP-1 mediated costimulatory activity". Support for the amendment is found in Example 21 (p.103, starting at line 12) which describes the effects of B7RP-1 on T cell costimulation.

Claim amendments are made solely to advance prosecution and without prejudice or disclaimer. Entry of the amendments is respectfully requested.

Applicant's Claim For Priority

The present application claims priority to U.S. Serial No. 09/264,527, filed March 8, 1999 and U.S. Serial No. 09/244,448, filed February 3, 1999. The Examiner alleges that Claims 35-44 and 46-54 which read on SEQ ID NO:16 and SEQ ID NO:17 are not entitled to the priority date of U.S. Serial No. 09/244,448 because there was no disclosure of the amino acid sequence of SEQ ID NO:16 and SEQ ID NO:17 in the '448 application. Applicant disagrees. The claims at issue recite antibodies which bind to SEQ ID NO:16 or SEQ ID NO:17. The '448 application discloses antibodies which bind to a polypeptide of SEQ ID NO:12, which polypeptide spans amino acid residues 1-288, with 14 fewer amino acids at the carboxy terminal end compared to the polypeptide of SEQ ID NO:16 and 17 having residues 1-302. Antibodies which bind to a polypeptide of SEQ ID NO:12 and to a polypeptide that comprises SEQ ID NO:12 would necessarily bind to the larger polypeptide

of SEQ ID NO:17. It is maintained that Applicant had possession of the invention as of the priority date of the '448 application.

Information Disclosure Statement

The Examiner has noted that, with the exception of references BK, BL and CO, all other copies of references cited in the Information Disclosure Statement of 5/16/2005 are missing from the file. Applicant submits herewith a PTO form 1449 with copies of references cited therein. Applicant also includes a supplementary PTO form 1449 listing additional family members of the originally submitted BK reference (WO 98/38216) and English equivalents of references BC, BD and BL. Copies of the foreign patent documents from the supplementary PTO form 1449 are included herewith. Applicant respectfully requests that the Examiner consider and make of record the cited references.

Rejections under 35 U.S.C. 112

Claims 33-44 and 47-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for the following reasons.

Claims 33-44 and 47-54 are alleged to be indefinite for recitations of "polypeptide of amino acids ... " and "polypeptide of Figure ... " as it is unclear whether the intended scope is closed language ("consisting of") or open language ("comprising of"). Solely to clarify the invention, Applicant has amended Claims 33-35 to recite "a polypeptide as set forth in Figure Applicant maintains that the scope of the claimed polypeptides is clear to one skilled in the art reading the specification. Applicant further notes that Claim 46, which was not rejected by the Examiner as indefinite, recites a polypeptide encoded by the nucleotide sequence of SEQ ID NO:11 or SEQ ID NO:16, which polypeptide is identical to that of SEQ ID NO:12 or SEQ ID NO:17, respectively. A reference to the polypeptide itself, rather than to the polypeptide encoded by the nucleotide sequence, does not cause the claim to become indefinite.

Claims 36 and 48-54 are alleged to be indefinite as the phrase "but does not bind" is unclear. Without acquiescing to the rejection, Claim 36 has been amended to delete the phrase "but does not bind".

Claims 37 and 48-54 are alleged to be indefinite as it is unclear to which sequences the antibody binds. Without acquiescing to the rejection, Claim 37 has been amended to further clarify the invention.

Claims 42 and 43 are alleged to be indefinite in the recitation of the terms "agonists" and "antagonists". The Examiner argues that the definition of the terms "agonists" and "antagonists" in the specification do not contemplate which activities of a B7RP1 protein are increased or decreased. Without acquiescing to the rejection and solely to clarify the claimed invention, Claims 42 and 43 have been amended to recite an increase or decrease in "B7RP-1 mediated immune costimulatory activity."

Claim 44 is alleged to be indefinite in the recitation of "immune costimulatory activity" as the term is not defined by the claim and the specification does not provide a sufficiently specific definition. Without acquiescing to the rejection, Claim 44 has been amended to recite "B7RP-1 mediated" immune costimulatory activity in order to more particularly claim the invention.

Claims 36, 37 and 48-54 are rejected under 35 U.S.C. 112, first paragraph, as the specification allegedly does not provide adequate written description for an antibody which binds human but not mouse B7RP-1 (claim 36), or an antibody which binds both human and mouse B7RP-1 (claim 37). The Examiner disputes Applicant's contention that the specification at p. 49-50 and Claim 13 supports the language in Claims 36 and 37. At p. 50, lines 11-14, the specification states that antibodies which react with B7RP-1 polypeptides are within the scope of the invention. The disclosure contemplates that an antibody may react with more than one distinct B7RP-1 polypeptide, such as, for example, with murine and human B7RP-1 polypeptides. It is well established that a literal recitation of the claim language is not required to be present in the specification as long as it is reasonably clear to one skilled in the art reading the specification that the Applicant had possession of the invention. *Vas-Cath Inc. v. Mahurkar* 19 USPQ2d 1117 (Fed. Cir. 1991). Applicant maintains that the specification provides adequate written description.

Claim 44 is rejected under 35 U.S.C. 112, first paragraph, as the specification allegedly does not enable an anti-B7RP1 antibody which inhibits immune costimulatory

activity. The Examiner argues that the specification has not taught how to make and use a B7RP1 antibody which (a) inhibits costimulatory activity of any costimulatory molecule and (b) inhibits any aspect of costimulation.

With respect to the argument in (b) above, the Examiner alleges that it would be highly unpredictable which subset of T cell functions, in addition to T cell proliferation, would be affected by B7RP1 or a B7RP1 antibody, citing Riley et al. (Blood 105, 13-21 (2004)) as evidence that T cell costimulation can involve a variety of cellular processes. T cell proliferation was used as a basis for an *in vitro* assay for B7RP1 activity in Example 17 of the specification. However, when tested *in vivo*, B7RP1 was shown to enhance immune responses as evidenced by more severe arthritis in mice being administered B7RP1 (Example 18), and by stimulation of enhanced cytolytic T cells and cellular immune functions to retard the growth of an immunogenic tumor (Example 20). Modulation of an immune response is a physiological response to costimulation. As noted by Riley et al. (p. 18, left hand column), "... costimulation dysfunction can play a role in the initiation, progression and pathogenesis of autoimmune diseases." Clearly, B7RP1 is able to modulate immune function through the B7RP1/CRP1 immune costimulatory pathway. A change in immune function is a primary response of the B7RP1/CRP1 pathway. Applicant maintains that the specification enables inhibition of costimulatory activity.


Without acquiescing to the rejection and solely to advance prosecution, Claim 44 has been amended to recite "B7RP-1 mediated" immune costimulatory activity.

CONCLUSION

Claims 33-44 and 47-54 are believed to be in condition for allowance and an early notice thereof is solicited.

Please send all future correspondence to:
US Patent Operations/RBW
Dept. 4300, M/S 28-2-C
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, California 91320-1799

Respectfully submitted,


Robert B. Winter
Attorney/Agent for Applicant(s)
Registration No.: 34,458
Phone: (805) 447-2425
Date: June 16, 2006